

REMARKS

Claims 1-35 are pending. In this amendment, claims 1-35 have been cancelled and claims 36-63 have been newly added in place thereof. No new matter has been added by these amendments.

Applicants submit that the Examiner acknowledged that the originally claimed subject matter was claimed in a Markush format and would be subject to restriction in accordance with *In re Harnisch*. Applicants submit also that the present claims being a subset of the original claims are also claimed in a Markush format and would also be subject to restriction in accordance with the (a) two-pronged test of *In re Harnisch*; and (b) must be examined according to the principles presented in the *Harnisch cases* (as discussed *infra*).

For the following reasons set forth below regarding *In re Harnisch* and the *Harnisch cases*. Applicants respectfully request reconsideration and withdrawal of the Restriction Requirement.

**I. Discussion of Election/Restriction**

The Offices's purported basis for requiring the Election/Restriction is that:

1. The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. For these reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. 121:

I. First, regarding claims 1-18, and 27 (in part), applicant must choose a specific ring for substituent Ar, including size and identity of each ring atom, classified in various classes of class 544, 546, and 548 depending on its identity.

II. Second, regarding claims 1-18, and 27(in part) applicant must choose a specific ring for substituent C, including size and identity of each ring atom, classified in various classes of class 544, 546, and 548 depending on its identity.

III. Third, regarding claims 18-26 and 28-35, applicant must choose one method of use to be examined with the above-mentioned compound and compositions claims classified in various subclasses of class 514 depending on the variables.

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may

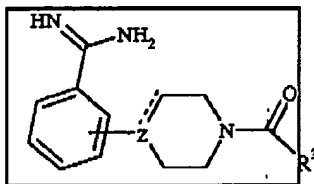
encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

Office Action at pages 2-3.

Applicants traverse the Election/Restriction. Markush-type claims, as recognized at page 2 of the Action, should be examined according to the principles set forth in *In re Harnisch*, 206 U.S.P.Q. 300, 631 F.2d 716, and related cases (hereinafter collectively referred to as *The Harnisch Cases*<sup>1</sup>). Applicants submit that the Election/Restriction is improper for failing to apply such principles.

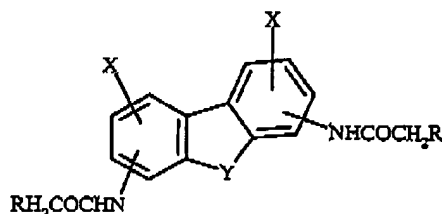
In particular, Applicants submit that *In re Harnisch* requires that an Election/Restriction of a Markush claimed invention must assess whether the compounds included within a Markush group (1) share a "common function", and (2) share a "single structural similarity", i.e., share a "core" portion of the molecule. See *In re Harnisch*, 206 U.S.P.Q. 300, at 305[4] and 305[5]. In the instant case, the Office has not provided any comment regarding how Applicants' claimed invention does not: (1) share a common function; and how it does not (2) share a single structural similarity.

To further the prosecution of the instant application, Applicants have amended the claims to more particularly define their claimed invention and submit that, again, this claimed subject matter is set forth in a Markush-type format and would only be appropriately restrictable using the criteria of *the Harnisch cases*. Additionally, Applicants submit that the newly amended claims are not restrictable because the subject matter encompassed therein all share a common function, i.e., the treatment of a patient suffering from a disease state capable of being modulated by inhibiting tryptase activity, and share a single structural similarity, i.e., share a single "core". That single "core" is encompassed within the boxed portion of the structure as follows:



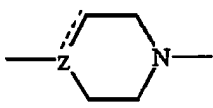
<sup>1</sup> The *Harnisch cases* collectively include: *In re Harnisch*, 206 U.S.P.Q. 300; *Ex parte Holt and Randell*, 214 U.S.P.Q. 381; *In re Haas*, 198 U.S.P.Q. 334 (Haas II); *In re Weber, Soder, and Boksay*, 198 U.S.P.Q. 328; *Ex parte Brouard Leroy, and Stiot*, 201 U.S.P.Q. 538; *In re Jones*, 74 U.S.P.Q. 149; and *Ex parte Dahlen and Zwilgmeyer*, 42 U.S.P.Q. 208.

Additionally, Applicants note that the single "core" set forth above having variables therein is also supported by *Ex parte Dahlen and Zwilgmeyer*, 42 U.S.P.Q. 208 (POBA, 1939), which was a case where variability in a core within a structure of the following formula was recognized to be proper,



i.e., variability in a constituent variable in the core structure, i.e., Y, was proper. That variable was defined in Markush format as a bivalent bridge radical including  $-\text{CH}_2-$ ,  $-\text{CO}-$ ,  $-\text{C}=\text{C}-$ ,  $-\text{CH}_2\text{CH}_2-$ ,  $-\text{NH}-$ ,  $-\text{N-alkyl}-$ ,  $-\text{O}-$ ,  $-\text{S}-$ ,  $-\text{N}=\text{N}-$ ,  $-\text{N}=\text{O}-$ ,  $-\text{SO}_2-$  and  $-\text{COCO}-$ . Particularly noteworthy regarding that compound was that the Markush grouping was found to be acceptable even though the variable provided for molecular variations in the size and classification of tricyclic ring systems thereof, i.e., the central ring could consist of 5 to 6 members and form one cyclohexadienyl ring, one phenyl ring, and five different heteroaryl rings. Thus, variations in the classification groupings encompassed by the compound did not provide sufficient basis for restriction where a markush claimed compound otherwise met the two prong requirements of *In re Harnisch*.

In particular, with respect to Applicants' newly submitted claim set, even though ring structure

“” allows for variability in both “Z” and in the degree of unsaturation in the ring, such is not improper under the teaching of *Ex parte Dahlen and Zwilgmeyer* which provides for a portion of the “core” ring feature to possess variability therein.

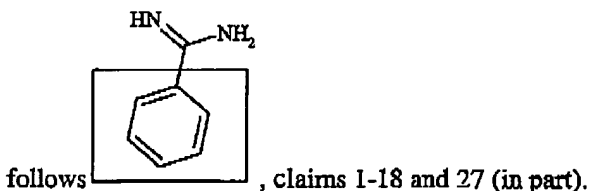
Applicants note that the Office has commented on particular structural features of Applicants' claimed invention to be “classified in various classes of class 544, 546, and 548 depending on its identity” upon setting forth Groups I, II, and III, at page 2 of the Action. Pursuant to *the Harnisch cases*, and in particular, *Ex parte Brouard, Leroy, and Stior*, 201 U.S.P.Q. 538, Applicants submit that the PTO Board of Appeals stated, that, “the fact that [six] different fields of search are involved [in that case] does not establish that the Markush group is improper.” Therefore, a Markush grouping rejection, i.e., a restriction requirement of a Markush claimed invention, is not proper by simply asserting that different fields of search may be involved.

Therefore, Applicants submit that the present restriction requirement is improper for failing to apply the criteria set forth in *the Harnisch cases*. Therefore, Applicants respectfully request withdrawal of the restriction requirement.

Applicants further submit that the subject matter now before the Office also: (a) meets the two-pronged test of *In re Harnisch* and is not subject to being restricted; and (b) must be examined according to the principles presented in *the Harnisch cases*.

## II. Provisional Election of a Group

To comply with the Office's Election/Restriction requirement, Applicants provisionally elect, with traverse, Group I, wherein Ar is enclosed within the boxed portion of the structure as

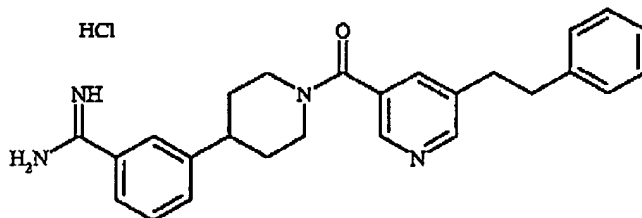


Applicants submit that once the compounds of the present invention are found to be novel, then the subject matter of Group III should be subject to rejoinder, pursuant to linking claim practice and the case law of *In re Ochai*.

Furthermore, Applicants affirm their right to file one or more divisional applications with respect to any of the non-elected subject matter should the restriction requirement be made final.

## III. Provisional Election of a Species

To comply with the Election of Species Requirement, Applicants elect the compound of Example 48, 3-[1-(5-phenylethyl-pyridine-3-carbonyl)-piperidin-4-yl]-benzamidinium hydrochloride, having the below formula,



Example 48

**IV. Miscellaneous**


Applicants submit that the discussion entitled "Rationale Establishing Patentable Distinctiveness Within Each Group" at pages 3-4 of the Action, has no bearing on the the application of criteria as set forth in the *the Harnisch cases*.

**VI. Conclusion**

Applicants believe that the foregoing constitutes a complete and full response to Action of record. The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. 18-1982 in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,

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Julie Anne Knight, Reg. No. 48,867  
Attorney for Applicant

sanofi aventis  
U.S. Patent Operations  
Route #202-206 / P.O. Box 6800  
Bridgewater, NJ 08807-0800  
Telephone (908) 231-3679  
Telefax (908) 231-2626

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